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KLEIN, O'NEILL & SINGH, LLP
43 CORPORATE PARK
SUITE 204
IRVINE, CA 92606

EXAMINER	
COLBERT, ELLA	
ART UNIT	PAPER NUMBER
3696	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/650,482	STEEN ET AL.	
	Examiner	Art Unit	
	Ella Colbert	3696	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-27 are pending. Claims 1 and 16 have been amended in this communication filed 09/11/08 entered as RCE and Amendment.

2. The Correspondence Address Change filed 06/20/08 has been entered.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/11/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 -27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites "the formulary records comprising chemical composition and properties of each of the medications, wherein the service center server is configured to … the plurality of formulary records comprising chemical composition and properties for

at least one of the orders for medication … for medication …" is not found in Applicants' specification. Claim 2 recites "each order record including order information for an order accepted and processed by the at least one pharmacy client system" is not found in Applicants' specification. Claims 3, 6, 7, 10, 15, and 16 have a similar issue. Applicants' are respectfully requested to point out where sufficient support for these claim limitations are found in the Specification.

Claim 2-15 and 17-27 are also rejected because of their dependency from a rejected claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "a service center client system" and nothing else is being done with the "service center client system" after the reference to it in lines 5 and 6 in the body of the claim. Claim 16 has a similar problem. Page 5, line 26-Page 6 line 1 recites "the service center server 21 is coupled and communicates with the service center client systems 25a-25c over a local area network or a wide area network using a wired communication media …". "…, the service center client systems 25a-25c are inside other networks mutually exclusive of the service center network 11." On page 6, lines 18-20 recites "medication orders are placed by the pharmacy client system 15 a-15d are transmitted to the pharmacy server 13". The global database is

discussed on Page 7, lines 5-12 and does not mention "order records". This section only references "request or order from a particular pharmacy for a particular patient and/or customer …".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson.

With respect to claim 1, Edelson teaches, A pharmaceutical administrative system comprising: a pharmacy network including a pharmacy server and at least one pharmacy client system, the at least one pharmacy client system configured to accept

and process orders for medications (col. 7, lines 16-27); and a service center network including a service center server and a service center client system, the service center network coupled to the pharmacy network and configured with a global database including a plurality of formulary records, the formulary records comprising chemical composition and properties of each of a plurality of medications (col. 7, lines 28-32), wherein the service center server is configured to supply the pharmacy server at least one of the plurality of formulary records comprising chemical composition and properties for at least one of the orders for medication upon request by the at least one pharmacy client system when the at least one of the orders for medication is processed (Fig.'s 6-7- show downloaded formulary information sent to a local pharmacist as part of drug order processing). Edelson did not expressly disclose "the formulary records comprising chemical composition and properties of each of a plurality of medications" as recited in claim 1. Nevertheless, the difference is only found in the non-functional descriptive material that does not alter the recited structural elements which remain the same regardless of the specific contents or type of records. Thus, this material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulak*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir.1994): MPEP 2106. MPEP 2106.01 recites "Descriptive material can be characterized as either "functional descriptive material" or "non functional descriptive material." "Functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical

relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993). "Nonfunctional descriptive material" includes but is not limited to music, literary works, and a compilation or mere arrangement of data". Formulary records, chemical composition are considered merely data which is considered non-functional descriptive material.

With respect to claim 2, Edelson teaches, wherein the global database further includes a plurality of order records, each order record including order information for an order accepted and processed by the at least one pharmacy client system (col. 10, lines 5 - col. 11, lines 1-15).

With respect to claim 3, Edelson teaches, wherein the global database further includes a plurality of customer records, each customer record including contact and formulary information for at least one customer (col. 14, lines 53- col. 15, lines 1-6, col. 17, line 65-col. 18, line 3 –global database, col. 19, lines 45-60, and col. 22, lines 55-65).

With respect to claim 4, Edelson teaches, wherein the global database further includes a plurality of patient records, each patient record including contact information and medication history for at least one patient (col. 16, lines 10-35, col. 19, lines 1-67, and col. 20, line 50-col. 21, line 3).

With respect to claim 5, Edelson teaches, wherein the pharmacy client system is further configured to generate a medication specific label containing medication identification information (col. 26, line 56-col. 27, line 8 and col. 28, lines 21-42).

With respect to claim 6, Edelson teaches, wherein the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database (col. 31, lines 8-21 and lines 51-62).

With respect to claim 7, Edelson teaches, wherein updates to the formulary records include modification to the ingredients of the medication (col. 32, lines 48-59).

With respect to claim 8, Edelson teaches, wherein updates to the modification to the ingredients of the medication include changes to amounts of caloric content in the medication (col. 32, lines 54-59).

With respect to claim 9, Edelson teaches, wherein updates to the modification to the ingredients of the medication include changes to amounts and preferences of electrolytes in the medication (col. 32, lines 54-59).

This dependent claim is rejected for the similar rationale given above for claim 8.

With respect to claim 10, Edelson teaches, wherein the pharmacy client system is configured to verify the updates to the formulary records in the global database (col. 35, lines 23-33).

Claims 11-13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson in view of "On-line Medical Dictionary".

With respect to claim 11, Edelson failed to teach, wherein the medication specific label is for an intravenous solution and the medication identification information includes a refractive index associated with the intravenous solution. "Online Medical Dictionary" teaches, wherein the medication specific label is for an intravenous solution and the

medication identification information includes a refractive index associated with the intravenous solution (page 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify in Edelson because such a modification would allow Edelson to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 12, Edelson failed to teach, wherein the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution. "Online Medical Dictionary" teaches, wherein the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution (page 4-"ratio"-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify in Edelson because such a modification would allow Edelson to use an intravenous solution for medical conditions such as dehydration to put the electrolytes back into a person's body.

With respect to claim 13, Edelson failed to teach, wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client. "Online Medical Dictionary" teaches, wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client (page 1). It would have been obvious to one having ordinary skill

in the art at the time the invention was made to modify in Edelson because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements.

With respect to claim 18, this dependent claim is rejected for the similar rationale as given above for claim 13.

With respect to claim 19, this dependent claim is rejected for the similar rationale given above for claim 18.

With respect to claim 20, this dependent claim is rejected for the similar rationale given above for claims 18 and 19.

Claims 11-13 and 18-20 are also considered non-functional descriptive claim language and are not accordingly given patentable weight.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson in view of "On-line Medical Dictionary" and further in view of (US 5,845,255) Mayaud.

With respect to claim 14, Edelson failed to teach, further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time. Mayaud teaches, further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the

backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time (col. 17, lines 44-52, col. 46, lines 16-31, and fig. 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Mayaud in Edelson because such an incorporation would allow Edelson to have a server system where the file server or database management server manages the data storage over a local area network.

With respect to claim 15, Edelson failed to teach, wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network. Mayaud teaches, wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network (col. 1, lines 46-67, col. 2, lines 1-11, and col. 6, lines 59-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Mayaud in Edelson because such an incorporation would allow Edelson to have preferred drugs that vary in content and usually determinative of the cost effectiveness of a prescription in a database.

With respect to claim 16, Edelson teaches, A pharmaceutical administrative system comprising: a pharmacy network including a pharmacy server and at least one pharmacy client system, the at least one pharmacy client system configured to accept

and process orders for medications (col. 7, lines 16-27); and a service center network including a service center server and a service center client system, the service center network coupled to the pharmacy network and configured with a global database including a plurality of formulary records, the formulary records comprising chemical composition and properties of each of a plurality of medications (col. 7, lines 28-32), wherein the service center server is configured to supply the pharmacy server at least one of the plurality of formulary records comprising chemical composition and properties for at least one of the orders for medication upon request by the at least one pharmacy client system when the at least one of the orders for medication is processed (Fig.'s 6-7- show downloaded formulary information sent to a local pharmacist as part of drug order processing). Edelson did not expressly disclose "the formulary records comprising chemical composition and properties of each of a plurality of medications as recited in claim 1. Nevertheless, the difference is only found in the non-functional descriptive material that does not alter the recited structural elements which remain the same regardless of the specific contents or type of records. Thus, this material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulak*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir.1994): MPEP 2106. MPEP 2106.01 recites "Descriptive material can be characterized as either "functional descriptive material" or "non functional descriptive material." "Functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical

relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993). "Nonfunctional descriptive material" includes but is not limited to music, literary works, and a compilation or mere arrangement of data". The "wherein" clause merely states the result of a limitation in the claim and is therefore given little patentable weight. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnes and Noble.com Inc.*, 57USPQ2d 1747 (Fed. Cir. 2001). Formulary records, chemical composition are considered merely data which is considered non-functional descriptive material.

wherein the at least one pharmacy client system comprises: an order maintenance unit configured to create an order for medication for at least one customer and at least one patient (col. 35, lines 1-22); a formulary unit coupled to the order maintenance unit and presenting information about the medication to the order maintenance unit (col. 35, lines 23-55); a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication; and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 12, lines 42-65, col. 35, line 57-col. 36, line 57 and fig's 6-11 and 15).

With respect to claim 17, Edelson teaches, wherein the medication is an intravenous solution (col. 25, lines 46-55).

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson and in view of (US 5,597,995) Williams et al, here after Williams and further in view of "Onliine Dictionary".

With respect to claim 21, Edelson failed to teach, wherein the order maintenance unit is configured to generate medication specific labels for the medication. Willaims teaches, wherein the order maintenance unit is configured to generate medication specific labels for the medication (col. 4, line 63-col. 5, line 33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Edelson with the teachings of Williams because such a modification would allow Edelson to have medication specific labels for the medication and to have a prescription delivery system to generate the invoice and label and other documentation prior to delivering the medication to the patient.

With respect to claim 22, Edelson failed to teach, wherein the medication specific labels for the medication includes information about a refractive index of the intravenous solution. Williams teaches, wherein the medication specific labels for the medication includes information about a refractive index of the intravenous solution (col. 5, lines 34-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Edelson with the teachings of Williams and "Online Dictionary" because such a modification would allow Edelson to have the medication specific labels for the medication include information about a refractive index of the

intravenous solution since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 23, Edelson failed to teach, wherein the medication specific labels for the medication includes information about a level of potassium in the intravenous solution calculated using flame photometry. Williams teaches, wherein the medication specific labels for the medication includes information about a level of potassium in the intravenous solution calculated using flame photometry (col. 5, line 62-col. 6, line 49 and col. 8, line 33-col. 9, line 41 and "Online Dictionary", Page 1, para.s 4 and 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Edelson with the teachings of Williams and "Online Dictionary" because such a modification would allow Edelson to have the medication specific labels include information about a level of potassium in the intravenous solution calculated using flame photometry to have a major intracellular action that is widely distributed in the body in muscle tissue, nerve tissue, blood cells, and plasma which is filtered in the glomerulus, absorbed in the proximal tubule and finally excreted by exchange for sodium in the distal tubule. The reliability depends on the proper maintenance of the flame photometer and the salient features. If low serum potassium values are observed due to low intake of dietary potassium over a period of time or increased loss through kidney, vomiting or diarrhea and increased secretion of adrenal steroids or some diuretics that promote the loss of potassium a flame photometer (digital flame photometer) for simultaneous measurement is useful in these medical conditions.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson and (US 5,597,995) Williams et al, hereafter Williams and "Online Dictionary" and further in view of (US 5,758,095) Albaum et al, hereafter Albaum.

With respect to claim 24, Edelson failed to teach, the pharmacy client system of claim 23, wherein the modifications to the ingredients of the medication includes modifications to caloric content of the medication. Albaum teaches, the pharmacy client system of claim 23, wherein the modifications to the ingredients of the medication includes modifications to caloric content of the medication (col. 10, lines 17-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Albaum in Edelson because such an incorporation would allow Albaum to know how many calories are in each portion of the medication and how many calories are being ingested each day especially if the patient is on a weight loss regime or has a medical condition that requires knowing how many calories are in each portion of the medication.

With respect to claim 25, this dependent claim is rejected for the similar rationale given above for claim 24.

With respect to claim 26, Edelson failed to teach, wherein the modifications to the ingredients of the medication includes modifications to electrolytes in the medication. "Online Dictionary" discloses wherein the modifications to the ingredients of the medication includes modifications to electrolytes in the medication (Page 1 of Page 1- discusses the ingredients can be modified by electrolysis). It would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify Edelson with the teachings of "Online Dictionary" because such a modification would allow Edelson to have substances that dissociates into two or more ions, to some extent, in water.

With respect to claim 27, this dependent claim is rejected for the similar rationale as given above for claim 26.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Engleson et al (US 20050107914) disclosed an online pharmacy network and pharmacy administration.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ella Colbert whose telephone number is 571-272-6741. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dixon Thomas can be reached on 571-272-6803. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ella Colbert/
Primary Examiner, Art Unit 3696

December 7, 2008